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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,077

04/28/2005

Kyung-Lim Lee

P27808

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7590

12/04/2006

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EXAMINER

GRAFFEO, MICHEL

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/533,077

Applicant(s)

LEE ET AL.

Examiner

Michel Graffeo

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 19-30 and 33-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 19-30 and 33-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Action

Claims 17, 19-30 and 33-39 are examined.

Applicant has amended claims 17 and 19, canceled claims 18 and 31-32, added claims 37-39 and provided arguments for the patentability of claims 17, 19-30 and 33-39 in the response filed 19 July 2006.

Applicant's arguments, see response, filed 19 July 2006, have been fully considered and are persuasive. Therefore, the rejections of claims 17-36 under 35 USC §112 have been withdrawn. However, after further consideration, new grounds of rejection are made. Any rejection not specifically stated in this Office Action has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-20, 33-36 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

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was filed, had possession of the claimed invention. This is a written description rejection.

Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. In particular, Applicant has not provided a description of the structure of a representative number of derivatives and/or isomers nor a description of the chemical and/or physical characteristics of a representative number of compounds which are derivatives and/or isomers nor a description of how to obtain a representative number of specific derivatives and/or isomers.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 26-29 rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,491,943 to Tsuji et al.

Tsuji et al. teach that catechins suppress histamine release (see col 2 lines 14-16) and can treat allergies also via a reduction in IgE. Asthma is discussed as an allergy which can be treated in col 1 lines 15-20. That HRF is not explicitly recited does not detract from the anticipatory nature of the reference since a compound and its properties are inseparable and that the catechins are administered and taught to have the effect as claimed, they necessarily function in the same way as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 19-30 and 33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamaguchi et al. TY-572, a Potent and Selective CD45 Inhibitor, Suppresses IgE-Mediated Anaphylaxis and Murine Contact Hypersensitivity Reaction, International archives of Allergy and Immunology (2001), 126 (4), 318-324 in view of US Patent No. 6,491,943 to Tsuji et al.

Hamaguchi et al. teach the use of a benzimidazole compound for the treatment of allergies such as anaphylaxis and urticaria comprising TU-572, which is considered a derivate of the claimed compounds (see Discussion page 322) and can be found on page 320 via a reduction in IgE. Further since compounds of identical chemical composition cannot have mutually exclusive properties a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present and to that end, the reference teaches a lipid-soluble weak base since the reference teaches a composition comprising the claimed compound.

Hamaguchi et al. do not teach the use of catechins.

Tsuji et al. teach that catechins suppress histamine release (see col 2 lines 14-16) and can treat allergies also via a reduction in IgE.

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach the claimed invention as claimed. One of ordinary

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skill in the art would have been motivated to combine Hamaguchi et al. with Tsuji et al. because both are directed to the treatment of allergies via IgE. Moreover, combining agents which are known to be useful as treatments for allergies individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Since it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining TU-572 and catechin flows logically from their having been individually taught in the prior art.

Response to Arguments - 35 USC § 103

Applicant's arguments, see response, filed 19 July 2006, with respect to the rejection(s) under 35 USC § 103 have been fully considered but are not persuasive. Applicant argues that the instant application is directed to a different mechanism of action for the treatment of allergies. That the Applicant identified a different mechanism of action is not a patentable difference between the references and the claimed subject matter. In particular, Applicant's note that the references teach the benzimidazole compounds as having CD45 inhibitory activity and not activity against IgE. Further, the method of inhibiting IgE as in claim 17 for example, is a necessary property of the compound whether or not it is known. Since products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties

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are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

Applicants also ask why Tsuji et al. is cited. Tsuji et al. is cited to teach that catechins suppress histamine release and can treat allergies also via a reduction in IgE.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

26 November 2006

MG

 12/1/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER